



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/008,957      | 01/20/98    | MORIARTY             | R <sup>mk</sup>     |

BULLWINKEL PARTNERS  
SUITE 1300  
19 SOUTH LASALLE STREET  
CHICAGO IL 60603-1493

HM12/0208

EXAMINER

BADIO, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

5

DATE MAILED: 02/08/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/008,957**

Applicant(s)  
**Moriarty et al.**

Examiner  
**Barbara Badio**

Group Art Unit  
**1616**



☒ Responsive to communication(s) filed on Dec 21, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above, claim(s) 7-9 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-6 and 10-14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1616

### **First Office Action on the Merits**

#### ***Election/Restriction***

1. Applicant's election with traverse of Group I, claims 1-6 and 10-14 and the species of figure 2, R group 13, in Paper No. 4 is acknowledged. The traversal is on the ground(s) that Groups I and III comprise a single inventive concept and are not patentably distinct. Applicant argues that the methods of claims 8 and 9 can not be practiced with another compound because of the unique efficacy of the claimed compound in preventing mammary lesion formation and its lower toxicity with reference to the present specification. Applicant also argues that the embodiment of R groups defined by compounds 13a-e are obvious variants. This is not found persuasive because the search required for Group I is not required for Group III and, thus a reference against the compound may not be applicable to the method of use of the compound. In addition, numerous compounds having vastly different chemical structures are known to be useful in the treatment of the various forms of cancer known in the art. Therefore, the process for using the claimed compounds can be practiced with materially different products.

Applicant's argument against the election requirement is noted. However, the examiner disagrees that the compounds of 13a-e are obvious variants. For example, a

Art Unit: 1616

reference against 13a would not be applicable to the compound of 13d if said reference lacks a teaching of equivalency between  $\text{CH}_3$  and  $\text{CF}_3$ .

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 7-9 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 4. It is noted that the search of the compounds has been extended to include the compounds of 13-13e, claims 2-6.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-6 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: formula I is not identified in the instant claims.

Art Unit: 1616

### ***Claim Objections***

5. Claims 10-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claims recite-" the compound of claim... with R or S stereochemistry at carbon centers C<sub>1</sub>, C<sub>3</sub>, C<sub>20</sub> and C<sub>24</sub>". The rotation at a chiral center can be of only two stereoisomeric forms (i.e., R or S). Claims 2-6 include compounds having either R or S stereochemistry at the recited chiral carbon centers. Therefore, claim 10-14 do not further limit the subject matter of claims 2-6 from which they depend.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holick et al. ('538).

Art Unit: 1616

Holick et al. teach a generic group of vitamin D derivatives useful in enhancing the healing of wounds, enhancing gastric, duodenal, esophageal, decubitus, genitourinary ulcer and ulcerative keratitis healing; inhibiting scar formation and treating periodontal disease (see Abstract). The compounds taught by the reference include vitamin D compounds of formula I wherein  $Y^1$  is ethyl,  $Z^1$  is hydrogen or  $X^1$ ,  $Q^a$  is  $CF_3$  or  $CH_2X^1$ ,  $Q^b$  is  $CF_3$  or  $CH_3$ , R is a double bond, W is  $CH-CH_3$ , V is  $CH_2$  and U is hydrogen (col. 3, line 64 - col. 4, line 31; col. 5, line 35 - col. 6, line 5; col. 7, lines 10-50; col. 9, line 48 - col. 10, line 51).

The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

8. Claims 1-6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holick et al. ('643).

Holick et al. teach a generic group of vitamin D derivatives useful in the treatment of psoriasis (see Abstract). The compounds taught by the reference include

Art Unit: 1616

vitamin D compounds of formula I wherein Y<sup>1</sup> is ethyl, Z<sup>1</sup> is hydrogen or X<sup>1</sup>, Q<sup>a</sup> is CF<sub>3</sub> or CH<sub>2</sub>X<sup>1</sup>, Q<sup>b</sup> is CF<sub>3</sub> or CH<sub>3</sub> and R is a double bond (col. 6, lines 1-54).

The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

9. Claims 1-6 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bishop et al. ('429).

Bishop et al. teach a generic group of vitamin D derivatives having antiproliferative and cell differentiation activity and are useful in the treatment of prostatic cancer and prostatic hyperplasia (see Abstract). The compounds taught by the reference include vitamin D compounds of formula I wherein B and C each are hydrogen, R<sup>1</sup> and R<sup>2</sup> are hydrogen, hydroxy, lower fluoroalkyl or lower alkyl, R<sup>3</sup> is lower alkyl, X<sup>1</sup> and X<sup>2</sup> each are hydrogen or hydroxyl (col. 5, line 28 - col. 6, line 40).

The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of

Art Unit: 1616

the genus taught by the reference , including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

10. Claims 1-4 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gulbrandsen et al. ('790).

Gulbrandsen et al. teach a generic group of vitamin D derivatives having useful in the treatment of myocardial failure (see Abstract). The compounds taught by the reference include vitamin D compounds of formula I wherein A and B each are hydrogen, R<sup>2</sup> and R<sup>3</sup> are hydrogen, hydroxyl or lower alkyl and R<sup>4</sup> is hydrogen or lower alkyl (col. 1, line 45 - col. 2, line 42).

The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference , including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

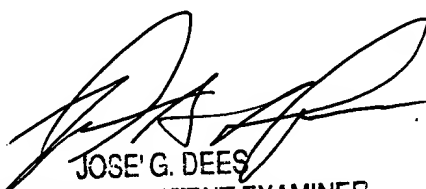
Art Unit: 1616

***Telephone Inquiry Contacts***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616

BB  
February 2, 1999